

REMARKS

FORMAL MATTERS:

Claims 1-13 and 19-26 are pending after entry of the amendments set forth herein.

Claims 14-18 were canceled in a prior amendment without prejudice.

Claim 7 is amended.

No new matter is added.

REJECTIONS UNDER §112, ¶2

Claims 7-13 are rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter.

Although applicants do not acquiesce to the rejection, applicants wish to create a spirit of cooperation with the Examiner. Accordingly, claim 7 have been amended in accordance with the language proposed by the Examiner thereby rendering the rejection moot.

REJECTIONS UNDER §103(A)

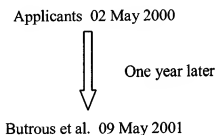
Claims 1, 5, 7-13, 19-23 and 25-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Drug Facts and Comparisons in view of Butrous et al. (EP 1 097 711).

The rejection is traversed as applied and as it might be applied to the presently pending claims because **Butrous is not prior art** with respect to the present application as explained in detail below.

The present application includes multiple claims to priority. One claim to priority is to application Serial No. 09/563,773 filed May 2, 2000. The '773 application issued as U.S. patent 6,428,769 on August 6, 2002. Within the '769 patent there is a section relating to aerosolized administration of sildenafil beginning at col. 8, line 39 and continuing to col. 9, line 21. Accordingly, applicants have clearly established a **priority date at least as early as May 2, 2000 with respect to a disclosure of aerosolized delivery of sildenafil to the lungs for the treatment of erectile dysfunction.**

The published European patent application 1,097,711 to Butrous et al. first published on May 9, 2001. This is after Applicant's priority date of May 2, 2000 to which applicants are clearly entitled to with respect to aerosolized delivery of sildenafil to treat erectile dysfunction.

Applicants understand that the Butrous et al. published European patent application claims priority dates to November 2, 1999, February 11, 2000 and November 11, 2000. However, those priority dates do not constitute prior art under any section of 35 U.S.C. §102. Accordingly, Butrous et al. is not prior art with respect to the present application regarding the subject matter for which it was cited. In view of such reconsideration and withdrawal the rejection is respectfully requested. Specifically, applicants understand that the Butrous et al. application would be prior art against the present application under the 35 U.S.C. §102(e) had the Butrous application been filed in the United States on November 2, 1999. However, it was only filed in Great Britain on November 2, 1999. The date Butrous et al. can be used as a reference is May 9, 2001 which is after applicants' claimed priority date.



Notwithstanding the above position it is pointed out that within the independent claims 1 and 19 applicants specifically claim a step of “diagnosing a human male patient as having erectile dysfunction.” The cited art to Butrous et al. is directed to treating pulmonary hypertension. Accordingly, there would be no reason to diagnose the patient as having erectile dysfunction.

Applicants recognize that paragraph 2 of the Butrous reference does refer to the compound sildenafil and indicates that it is sold under the trademark ViagraTM. This statement is accompanied by the following phrase “which has proven to be outstandingly successful as the first orally effective treatment for MED.” The remainder of the disclosure relates to the treatment of pulmonary hypertension. There is no disclosure within Butrous with respect to intrapulmonary delivery of sildenafil for the treatment of erectile dysfunction.

The Examiner is well aware that company's such as Pfizer typically disclose each and every possible means of administration and each and every indication which that means of administration might be used to treat. Thus, if pulmonary administration of sildenafil for the treatment of erectile dysfunction had been contemplated such would be disclosed and described within Butrous – and it is not mentioned. Clearly Butrous et al. did not contemplate such and as such this disclose as taken alone or in

combination with the “Drug Facts and Comparisons” does not anticipate or render obvious applicants invention as currently claimed.

Butrous et al. merely provide for a focused teaching of inhalation of sildenafil for the rapid treatment of PAH. The rapid treatment of PAH is obtained by administering the drug directly to the target organ, i.e. direct delivery to the lung. Butrous et al. do not propose systemic delivery of any drug and as such do not make it obvious that inhalation of sildenafil would provide for any systemic effects such as rapid treatment of erectile dysfunction. Butrous et al. specifically do not teach that inhaling sildenafil would have a systemic effect on erectile dysfunction which would be more rapid as compared with oral vasodilators. The ability to obtain rapid treatment for erectile dysfunction with any drug depends on properties of the drug. Some drugs are absorbed rapidly from the lungs while others are absorbed rapidly from the gut. Had Butrous et al. noticed that inhalation of sildenafil provided for rapid treatment of erectile dysfunction such would be disclosed and described within this publication – and it is not.

REJECTIONS UNDER §103

Claims 2-4, 6 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drug Facts and Comparison in view of Butrous et al. (EP 1 097 711) as applied to claims 1, 5, 7-13 and 19-23 and 25-26 above and further in view of Blood et al. (U.S. Patent 6,579,968). Blood et al. is not prior art to the present claims as described in detail below.

The earliest possible priority date on which Blood et al. could rely would be June 29, 1999. Blood et al. has apparently been cited in the rejection in support of a disclosure of intrapulmonary administration of a hormone. However, applicants have a priority date of May 4, 1999 in provisional application 60/132,472 which supports the treatment of erectile dysfunction by the intrapulmonary delivery of hormones. Accordingly, with respect to the subject matter of intrapulmonary delivery of hormones Blood et al. is not prior art to the present application. In view of such the rejection should be reconsidered and withdrawn.

In addition to the position provided here with respect to the earlier priority of the present application applicants refer to the arguments above with respect to why the claims now pending are patentable over the combination of references as cited within either of the 35 U.S.C. §103 rejections.

SUMMARY

Claim 7 was amended to overcome the 35 U.S.C. §112 rejection. The 35 U.S.C. §103 rejection based on both Blood et al. and Butrous et al. should be reconsidered and withdrawn in view of the priority date of the present application relative to the priority date of Blood et al. and Butrous et al. with respect to the issues for which Blood et al. and Butrous et al. were cited. Butrous et al. contains no teaching or suggestion that sildenafil should be administered by the intrapulmonary route in order to obtain rapid treatment of erectile dysfunction. As such the 35 U.S.C. §103 rejection should be reconsidered and withdrawn.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number AERX-080CIP2.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: 1/MARCH/07

By: [Signature]

Karl Bozicevic
Registration No. 28,807

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231